

# Risedronate for the prevention of bone loss after steroid therapy for a flare-up in inflammatory bowel disease

<b>Submission date</b> 16/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/10/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
2004-004325-10

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
ME/2005/2018; 2004-004325-10

# Study information

## Scientific Title

A randomised controlled trial to evaluate whether a short course of once weekly risedronate prevents bone loss following high-dose steroid therapy for an acute exacerbation of inflammatory bowel disease

## Study objectives

The hypothesis is based on the observation that osteoporosis occurs in patients with inflammatory bowel disease (IBD) and that detectable bone loss occurs after steroid treatment for only 8 weeks. Bisphosphonates are effective at treating bone loss but whether it is effective at preventing bone loss in this context is being addressed in this trial.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Gloucestershire Research Ethics Committee approved the trial in June 2005 (ref: 05/Q2005/74)

## Study design

Randomised, double-blind, placebo controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Inflammatory bowel disease (ulcerative colitis and Crohn's disease)

## Interventions

All patients participating in the trial were given calcium and vitamin in the form of Cacit D3 effervescent granules (calcium 500 mg/Vitamin D 440IU) at a dose of one sachet daily. Patients were randomised to risedronate 35 mg weekly or a placebo.

The total duration of intervention was 8 weeks and follow up was for the same 8 weeks in both arms. Participants were seen at baseline and then 8 weeks.

## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Risedronate

**Primary outcome measure**

The difference in percentage change in total hip (and sub-regions of the hip) and lumbar spine bone mineral density (BMD) measured by dual x-ray absorptiometry (DXA) 8 weeks apart between treatment groups (baseline is when corticosteroids start and week 8 at completion of the steroids).

**Secondary outcome measures**

1. Do patients with ulcerative colitis and Crohn's disease have a differential response to steroid therapy or risedronate?
2. Change in markers of bone turnover (CTX for resorption and P1NP for formation) measured before steroids start (week -1), baseline and at week 8
3. Urinary steroid metabolites and cytokines measured from samples obtained at week -1

**Overall study start date**

01/10/2005

**Completion date**

30/09/2007

**Eligibility****Key inclusion criteria**

1. Aged greater than or equal to 16 years, either sex
2. Ulcerative colitis and Crohn's disease
3. Experiencing a relapse
4. Requiring steroid therapy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Aged under 16 years
2. Use of corticosteroids in the preceding 3 months
3. Evidence of osteoporosis (known vertebral fracture, T score less than -2.5)
4. Pregnant and lactating women

5. Women of childbearing age will be eligible provided they use reliable contraception
6. Bone active therapy within previous 12 months (excluding calcium and low dose vitamin D)
7. Previous treatment with a bisphosphonate at any time
8. Associated disorder which may influence bone metabolism
9. Lactose intolerance

**Date of first enrolment**

01/10/2005

**Date of final enrolment**

30/09/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Academic Rheumatology**

Bristol

United Kingdom

BS10 5NB

## **Sponsor information**

**Organisation**

University Hospitals Bristol NHS Foundation Trust (UK)

**Sponsor details**

c/o Dr Maria Palmer

Director of Research and Effectiveness Department

Bristol Royal Infirmary

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04nm1cv11>

# Funder(s)

## Funder type

Industry

## Funder Name

Procter and Gamble Pharmaceuticals (UK) - educational grant.

## Funder Name

The funder had no input into the study design, recruitment or the analysis of the results.

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2010		Yes	No